

CLAIMS

WE CLAIM:

- 5 1. A fast dissolving tablet which comprises a therapeutically effective amount of drug(s) that acts as a cyclooxygenase-2 (COX-2) inhibitor for oral administration.
- 10 2. The tablet according to claim 1 wherein the tablet comprises a therapeutically effective amount of COX-2 inhibitor, a filler and optionally, other pharmaceutical excipients. *✓ 145 2 51*
- 15 3. The tablet according to claim 1 wherein the fast dissolving tablet dissolves in the mouth.
4. The tablet according to claim 1 or 2 wherein the drug(s) that acts as a cyclooxygenase-2 (COX-2) inhibitor is specific or preferential COX-2 inhibitor.
- 20 5. The tablet according to claim 4 wherein the COX-2 inhibitor is selected from the group consisting of meloxicam, rofecoxib, celecoxib, valdecoxib, parecoxib, nabumetone, nimesulide and etodolac.
- 25 6. *EP 628/4* The tablet according to claim 2 wherein the filler may be selected from the group consisting of alkali earth metal salts, carbohydrates, celluloses, starches, clays and polyethylene glycols, and mixtures thereof. *✓ 029 8152*
- 30 7. The tablet according to claim 9 wherein the filler may be selected from the group consisting of directly compressible dicalcium phosphate dihydrate, tricalcium phosphate, calcium sulfate, calcium carbonate, calcium hydroxide, aluminium hydroxide, magnesium silicate, aluminium magnesium hydroxide, maltose, maltitol, sorbitol, mannitol, glucose, sucrose, xylitol, lactose, lactose monohydrate, erythritol, fructose, maltodextrins, microcrystalline cellulose, calcium carboxy methyl *✓ 029 8146*
7 628/4

10085664.022702

cellulose, pregelatinized starch, potato starch, maize starch, kaolin, polyethylene glycol 4000, and mixtures thereof.

8. The tablet according to claim 2 wherein the pharmaceutical excipients comprises binders, disintegrants, lubricants, glidants, colouring agents, flavouring agents and sweeteners. *EP 629/4*
9. The tablet according to claim 8 wherein the binders may be selected from the group consisting of microcrystalline cellulose, mannitol, *8/45* microcrystalline dextrose, directly compressible dicalcium phosphate, amylose and polyvinylpyrrolidone. *EP 629/4*
10. The tablet according to claim 8 wherein the disintegrant is selected from the group consisting of starches or modified starches, clays, celluloses, *7/50* algin, cross-linked celluloses, gums, cross-linked polymers, effervescent agents, and mixtures thereof.
11. The tablet according to claim 10 wherein the disintegrant is selected from the group consisting of sodium starch glycolate, corn starch, potato starch, pregelatinized starch, bentonite, montmorillonite, veegum, microcrystalline cellulose, hydroxypropyl cellulose, carboxymethyl cellulose, sodium alginate, alginic acid, croscarmellose sodium, guar gum, xanthan gum, crospovidone; sodium bicarbonate and citric acid, and mixtures thereof. *EP 629/4*
12. The tablet according to claim 8 wherein the lubricants may be selected from the group consisting of talc, magnesium stearate, calcium stearate, stearic acid, magnesium lauryl sulphate and hydrogenated vegetable oil, sodium benzoate, sodium acetate, sodium chloride, leucine, sodium stearyl fumarate, PEG 4000, and mixtures thereof. *EP 629/4*
13. The tablet according to claim 8 wherein the glidants may be selected from the group consisting of colloidal silicon dioxide and talc. *EP 629/4*

14. The tablet according to claim 8 wherein the colouring agents may be selected from any colorant used in pharmaceuticals which is approved and certified by the FDA.

5 15. The tablet according to claim 8 wherein the flavouring agent may be selected from the group consisting of natural and artificial flavours, mints and essential oils or the mixtures thereof. *RP 629*

10 *Substantive* 16. The tablet according to claim 15 wherein the flavouring agent may be selected from the group consisting of peppermint, menthol, artificial vanilla, cinnamon, various fruit flavours, both individual and mixed, thymol, eucalyptol and methyl salicylate and the like.

15 17. The tablet according to the claim 8 wherein the sweetener may be selected from the group consisting of natural and artificial sweeteners.

20 18. The tablet according to the claim 17 wherein the sweetener may be selected from the group consisting of monosaccharides, disaccharides, polysaccharides, partially hydrolyzed starch, corn syrup solids, sugar alcohols, water-soluble artificial sweeteners, and mixtures thereof.

25 19. The tablet according to the claim 18 wherein the sweetener may be selected from the group consisting of xylose, ribose, glucose, mannose, galactose, fructose, dextrose, sucrose, maltose, sorbitol, xylitol, mannitol, soluble saccharin salts, cyclamate salts, acesulfam-K and free acid form of saccharin and dipeptide based sweeteners, and mixtures thereof.

30 *629/4* 20. A mouth dissolving tablet of COX-2 inhibitor consisting of a COX-2 inhibitor, croscarmellose sodium, mannitol, aspartame, colloidal silicon dioxide, magnesium stearate and flavouring agent.

21. A process for preparing a fast dissolving tablet according to claim 2 comprising the steps of:

- (a) blending a therapeutically effective amount of COX-2 inhibitor, a filler, and optionally, other pharmaceutical excipients;
- (b) compressing the homogeneous mixture obtained in step (a).

5 22. The process according to claim 21 wherein the blend is granulated before compression.

23. The process according to claim 22 wherein the granulation is done by wet or dry granulation methods.

10

24. The process according to claim 23 wherein the dry granulation is done by slugging or roller compaction.

20/220-4958001